REMARKS

Claims 1-55 were pending before this amendment. Claims 1-34 and 38-55 have been canceled without prejudice to pursue them in one or more continuation applications. Claims 35-37 have been amended to an independent claim format.

The claim rejections under 35 U.S.C. § 103(a) for obviousness

A. Claims 1-55 have been rejected as obvious over U.S. Patent Publication No. 2002/0127277 in view of Remingtons' Pharmaceutical Sciences (1990) ("Remington").

According to the Examiner, the '277 application discloses: (1) valproate compounds and derivatives encompassing all of the instantly claimed active agents, (2) compressed tablets prepared by mixing the active agent with a binder, and (3) a composition comprising the claimed active agent and excipients such as diluents. Further, the Examiner contends that the '277 application discloses the claimed component amounts, and recognizes the use of valproic acid for the treatment of mania, pain and epilepsy. *See,* Office Action, page 3. According to the Examiner, the '277 application discloses an immediate release dosage form based on the dissolution results shown in Example 1. The Examiner acknowledges that the '277 application does not disclose hydroxypropyl cellulose.

According to the Examiner, Remingtons' discloses binder materials employed in compressible tablets, including hydroxypropyl cellulose. The Examiner contends that Remingtons' suggests that hydroxypropyl cellulose is equivalent to the cellulose binders disclosed in the '277 application. Thus, according to the Examiner, it would have been obvious to use any of the binding materials disclosed in the '277 application or Remingtons' (e.g., hydroxypropyl cellulose) to arrive at the instantly claimed dosage forms and methods. *See,* Office Action, page 4.

B. Claims 1-55 have been rejected as obvious over the '277 application and Remingtons' in view of U.S. Patent No. 5,049,586; and

C. Claims 1-55 have been rejected as obvious over the '277 application and the '586 patent in view of Remingtons'.

The Examiner contends that the '586 patent discloses compressed tablets comprising valproic acid and excipients such as binders, disintegrants, lubricants, and fillers. Further, the Examiner contends that the '586 patent discloses an immediate release dosage form. The '586 patent does not disclose valproic acid salts, valproic acid derivatives, and hydroxypropyl cellulose. According to the Examiner, it would have been obvious to combine the teachings of the '586 patent with the '277 patent (discloses, e.g., the full range of active agents) and Remingtons' (discloses hydroxypropyl cellulose) to arrive at the instantly claimed solid dosage forms and methods.

Applicants respectfully traverse rejections (A)-(C), above. The rejections are moot in view of canceled claims 1-34 and 38-55. Further, no combination of the references discloses or suggests the formulations recited in claims 35-37.

Claim 35 is directed to: (a) uniform admixture of 500 mg/tablet N-(2-Propylpentanoyl) glycinamide; 50 mg/tablet hydroxypropyl cellulose; and 100 mg/tablet a microcrystalline cellulose, and (b) 55 mg/tablet croscarmellose sodium; 145 mg/tablet lactose; and 6 mg/tablet magnesium stearate.

Claim 36 is directed to: (a) a uniform admixture of 500 mg/tablet N-(2-Propylpentanoyl) glycinamide; 50 mg/tablet hydroxypropyl cellulose; and 100 mg/tablet a microcrystalline cellulose, and (b) 50 mg/tablet croscarmellose sodium; 145 mg/tablet lactose; and 6 mg/tablet magnesium stearate.

Claim 37 is directed to: (a) a uniform admixture of 250 mg/tablet N-(2-Propylpentanoyl) glycinamide; 25 mg/tablet hydroxypropyl cellulose; and 50 mg/tablet microcrystalline cellulose; (b) 450 mg/tablet microcrystalline cellulose; 50 mg/tablet croscarmellose sodium; and 6 mg/tablet magnesium stearate.

No combination of the references discloses or suggests an immediate release tablet comprising the specific components in the specific amounts recited in claims 35-37. There would be far less than a reasonable expectation that an ordinarily skilled artisan would select N-(2-Propylpentanoyl) glycinamide as the active agent from among valproic acid and derivatives thereof disclosed in the '277 application, and combine it with microcrystalline cellulose, croscarmellose sodium lactose, and magnesium stearate (also disclosed in '277), and then look to Remingtons' and

select hydroxypropyl cellulose from among all the disclosed cellulose materials. Even less likely is the expectation that an ordinarily skilled artisan would combine these components in the recited uniform admixture and in the recited amounts. The '586 patent does not disclose N-(2-Propylpentanoyl) glycinamide nor does it suggest the specific combination of excipients recited in claims 35-37. Thus, no combination of the references discloses or suggests the claimed formulations.

Accordingly, for the reasons stated above, the obviousness rejections should be withdrawn.

Conclusion

No new matter has been added by these amendments. In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

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